REMARKS

The present invention relates to a blood coagulation reagent kit capable of detecting lupus-anticoagulant in blood.

In the Office Action of December 15, 2006, claims 1 - 21 were rejected and claims 22 and 23 were withdrawn from consideration.

Claims 1, 4, 6 - 14, and 19 - 21 were rejected under 35 U.S.C. §102(b) based on U.S. Patent 5,314,095 (Brown) in light of Webster's Dictionary. Claims 1 - 6 and 8 - 13 were rejected under 35 U.S.C. §102(b) based on Smirnov (originally cited by the Examiner in the Office Action of March 29, 2006) in light of Webster's Dictionary. Lastly, claims 1, 4, and 6 - 21 were rejected under 35 U.S.C. §103(a) based on Brown and Webster's Dictionary in light of U.S. Patent 6,395,501 (Rosen).

Hereinabove, Applicants have amended the specification and the claims. It is respectfully submitted that the amended application and the claims now pending in view thereof meet all statutory requirements and are in condition for allowance.

First, regarding the amendment of the specification at page 6 and in claim 15, for technical accuracy, the spelling "sellaite" has been replaced by the correct spelling "celite". The former quoted term has the same pronunciation as the latter in the original Japanese application.

However, based on the reference to other related activator compounds such as the ellagic acid, kaolin, and silica, for example, as set forth in claim 3 and in the abstract of U.S. Patent 6,417,004, and claim 12 and lines 45 - 48 at column 2 of U.S. Patent 6,451,610, a person skilled in the art would immediately realize the error and realize that the correct intended compound is "celite". It would also be realized by a person skilled in the art that the magnesium fluoride mineral known as "sellaite" would not work as an activator.

In the amendments to the claims hereinabove, claims 1 - 5, as well as non-elected claims 22 and 23, have been cancelled. Therefore, the dependency of the several claims have been changed to depend on independent claims 8 or 21. Furthermore, in claim 8, the range of concentration of the phosphatidylserine has been narrowed based on the previous recitation of claim 21, thereby clearly differentiating the first reagent from the third reagent in the kit of current claim 8. Claims 10, 11, 12, and 14 have been amended to improve the grammatical format thereof. Lastly, new claims 24 - 27 have been added, directed to preferred embodiments of claim 21. Support for claim 24 may be seen by reference to claims 9 and 10, for claim 25 based on claim 16, for claim 26 based on claim 19, and for claim 27 based on claim 6.

The patentability of the amended claims herein maybe further understood by reference to the detailed discussion below, contrasting to the present invention to the prior art cited in the Office Action. Based thereon, it will be seen that the amended claims 6 - 21 and 24 - 27 are patentable over the cited art of record.

(1) U.S. Patent 5,314,095 (Brown)

Brown discloses prothrombin time reagents containing phosphatidylcholine (PC), phosphatidylethanolamins(PE), phosphatidylserinea(PS) and phosphatidylglycerol(PO) as phospholipids having various ratios of the phospholipids (PC:PE:PS:PCI) in tablet 1. Furthermore, Brown discloses addition of $CaCl_2$ to the reagents when measuring prothrombin time.

However, Brown fails to disclose a reagent kit prepared by combining two reagents each of which has a specific PS concentration, the PS concentration being different from each other. Furthermore, Brown does not teach or suggest that lupus anticoagulant (LA) can be detected by measuring coagulation times using a combination of two reagents having specific different PS content ratio from each other.

Therefore, Brown does not disclose the reagent kit of claim 8 of the present application, viz., the kit comprising a first reagent containing phosphatidylserine having a concentration in the range of 30 μg/ml to 1000 μg/ml and a third reagent containing phosphatidylserine having a concentration in the range of 0.2 μg/ml to 20 μg/ml. Brown does not disclose that the lupus anticoagulant is detected based on a first coagulation time obtained by using the first and second reagents, and a second coagulation time obtained by using the third and fourth reagents, either.

Accordingly, claim 8 and the claims dependent thereon are not anticipated by Brown.

(2) Smirnov

Smirnov discloses a reagent containing phospholipids vesicle for prothrombinase assay. Smirnov discloses in Fig. 1 that the thrombin was measured using a chromogenic assay by reacting the vesicles containing various concentrations of PS with factor Va, Xa, and prothrombin. Smirnov also discloses that he examined the influence of LA on the prothrombinase assay.

However, Smirnov fails to disclose a reagent kit prepared by combining two reagents, each of which has a specific PS concentration, and the PS concentrations being different from each other. Furthermore, Brown does not teach or suggest that LA can be detected by measuring coagulation times using a combination of two reagents having specific different PS content ratios from each other.

Therefore, in common with Brown, Smirnov does not disclose the reagent kit of claim 8 of the present application. Accordingly, claim 8 and claims 6 and 9 - 20 dependent thereon (directly or indirectly) are not anticipated by Smirnov.

(1) U.S. Patent 6,359,501 (Rosen)

Rosen discloses a method of quantitative determination of the functional activity of components of the Protein C anticoagulant pathway.

However, Rosen is silent about a reagent kit prepared by combining two reagents each of which has a specific PS concentration, the PS concentrations being different from each other. Furthermore, Brown does not teach or suggest that LA can be detected by measuring coagulation times using a combination of two reagents having specific PS content ratios different from each other. Therefore, in common with Brown, Rosen does not disclose the reagent kit of claim 8 of the present application.

Accordingly, even if Rosen is combined to Brown, it would not be obvious for the ordinary artisan to make the reagent kit of claim 8 of the present application.

Analogous to the situation regarding claim 8, claim 21 and its dependent claims are patentable under the properly applied standards of 35 U.S.C. §102(b) and §103.

In view of the above, reconsideration and allowance of pending claims 6 - 21 and 24 - 27 of this application are now believed to be in order, and such actions are hereby earnestly solicited.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

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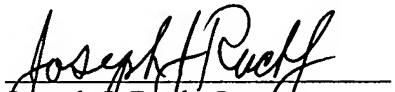
Respectfully submitted,



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Date: April 16, 2007